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May 10, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Draft Guidance for Industry on Improving Information
About Medical Products and Health Conditions
(Docket No. 2004D-0042)

Dear Sir/Madam:

We are writing on behalf of America's Health Insurance Plans (AHIP) to provide comments on the Draft Guidance for Industry on Improving Information About Medical Products and Health Conditions (the "Draft Advertising Guidance"). A notice of the Draft Advertising Guidance was published by the Food and Drug Administration (FDA) in the *Federal Register* on February 10, 2004.

AHIP is the national association representing the private sector in health care. AHIP's nearly 1,300 member companies provide health, long-term care, dental, vision, disability, and supplemental coverage to over 200 million Americans.

The development and use of new types of prescription drugs have increased substantially over the past decade, resulting in significant changes in the treatment of a wide number of health conditions and improved patient outcomes. Recent studies indicate that the pharmaceutical industry spent $2.7 billion on direct-to-consumer (DTC) advertising in 2001. The amount spent on DTC advertising has increased by approximately 145% between 1997 and 2001.[1]

The FDA's initial publication of broadcast guidelines in 1997 had the effect of encouraging broadcast advertising for prescription drugs to consumers. Because of the role DTC advertising has assumed for consumers, it is vital that the information provided about prescription drugs and medical devices be balanced and clear and describe their appropriate use, benefits, and risks.

The Draft Advertising Guidelines will help assure that consumers have the tools they need to make informed decisions – in consultation with their prescribing medical providers – about the most effective and appropriate treatment alternatives.

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[1] U.S. General Accounting Office, "Prescription Drugs: FDA Oversight of Direct-To-Consumer Advertising Has Limitations," GAO-03-177, October 2002.

AHIP believes, however, that there are a number of additional clarifications that could be made in the guidelines regarding DTC advertising:

- **We recommend that advertising directed to consumers must be communicated in a manner that is most likely to be understood by the average consumer.** The proposed guidelines only recommend that advertisements be communicated in a way that is understandable by a lay reader and presented in an easily readable format. The FDA should make clear that print and electronic advertisements intended for consumers may be subject to challenge by the agency if such advertising is communicated in a manner that is confusing, highly technical, or not likely to be understood. For this reason, we also recommend that "reminder" promotions that call attention to the name of a prescription drug but do not include indications, dosages, recommendations or other representations or suggestions about the drug are not appropriate because such advertisements do not provide consumers with information necessary to make decisions about medical treatments. If reminder promotions are allowed, they should, at the very least, contain information on the intended uses and potential risks for the prescription drug.
- **Provide that equal weight in terms of description should be given to both the risks and benefits of a prescribed drug or medical device.** Some advertisements may provide easily understood "benefits" for a particular drug or device while communicating risk information in a highly technical manner using small print. The guidelines should clarify that both the benefits and the risks be communicated in a manner that allows consumers to give equal weight to both the positive and negative attributes of a prescription drug or medical device.
- **Clearly state that other treatment alternatives are available.** The guidelines are helpful in advising pharmaceutical manufactures to include a statement that the consumer should consult with a medical professional about the prescription drug or medical device. DTC advertisements should also inform consumers – where appropriate – that other treatments may be available for the particular disease state or medical condition that is addressed by the drug or device.
- **Provide a clear definition of "close in time" or "close physical proximity."** The Draft Advertising Guidelines regarding "help seeking" or other disease awareness communications outlines the issues related to combining such advertisements with a separate advertisement for a prescription drug that is intended to treat a particular disease or medical condition (i.e., "bookend advertisements"). We believe the FDA should provide clear guidance on the appropriate interval between disease awareness advertising and prescription drug advertising. For example, it may be appropriate to prohibit disease awareness advertisements from appearing in the same publication (for print media) or within the same program (for electronic media) of an advertisement for a prescription drug intended to treat that disease.

Finally, we note that the Draft Advertising Guidelines are voluntary and are not binding on pharmaceutical manufacturers. AHIP recommends that the FDA consider whether it is appropriate to incorporate these guidelines into the agency's rulemaking process.

We also support efforts by the Department of Health and Human Services and by FDA to improve regulatory oversight of DTC advertising.

AHIP and its member companies believe that consumers must have access to information about health conditions and the availability of cost effective and appropriate treatment alternatives. Although AHIP supports the Draft Advertising Guidelines, we ask that the above recommendations be considered by the FDA as additional clarifications.

We appreciate the opportunity to comment on the Draft Advertising Guidelines. Please feel free to contact us if you have any questions.

Sincerely,

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